Exhibit 6

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

NOV 6 2013

VIA HAND DELIVERY

Notification of Opportunity to Initiate a Voluntary Recall

Mr. Jacob Geissler
CEO and Co-Owner
USPlabs, LLC
10761 King William Drive
Dallas, Texas 75220-2445

Dear Mr. Geissler:

Pursuant to section 423 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 3501), as amended by the FDA Food Safety Modernization Act, the U.S. Food and Drug Administration (FDA) is providing your firm, USPlabs, LLC, with an opportunity to voluntarily cease distribution and conduct a recall of the below referenced OxyElite Pro dietary supplement products manufactured for and distributed by your firm from November 2012 through October 2013. Section 423(a) of the FD&C Act provides in relevant part that if FDA "determines...that there is a reasonable probability that an article of food (other than infant formula) is adulterated under section 402 [of the FD&C Act]... and the use of or exposure to such article will cause serious adverse health consequences or death to humans," before taking further action under section 423 of the FD&C Act, FDA must offer the responsible party the opportunity to voluntarily cease distribution and recall such articles (21 U.S.C. 3501(a)).[1]

As discussed further below, FDA has determined that there is a reasonable probability that the following products (collectively, "OxyElite Pro" or "the OxyElite Pro products") manufactured for your firm by SK Laboratories, Inc., at their Anaheim, California, facility are adulterated under sections 402(f)(1)(A)[2] and (B)[3] of the FD&C Act (21 U.S.C. 342(f)(l)(A) and (B)) and a reasonable

[1] The term "responsible party" is defined in section 417 of the FD&C Act and refers to the person who submits the registration for a food facility that is required to register under section 415(a) of the FD&C Act (21 U.S.C. 350d), at which the food at issue is manufactured, processed, packed or held. On May 26, 2010, you registered USPlabs with FDA pursuant to section 415(a) of the FD&C Act (21 U.S.C. 350d(a)). This registration was renewed on October 24, 2012. As such, this letter is directed to you as the responsible party.

[2] Under section 402(f)(l)(A) of the FD&C Act (21 U.S.C. 342(f)(1)(A)), a food shall be deemed adulterated if "it is a dietary supplement or contains a dietary ingredient that presents a significant or unreasonable risk of illness or injury under (i) conditions of use recommended or suggested in labeling, or (ii) if no conditions of use are suggested or recommended in the labeling, under ordinary conditions of use."

[3] Under section 402(f)(1)(B) of the FD&C Act (21 U.S.C. 342(f)(1)(B)), a food shall be deemed adulterated if "it is a dietary supplement or contains a dietary ingredient that is a new dietary ingredient for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury."

probability that the use of or exposure to these products will cause serious adverse health consequences or death to humans:

- OxyElite Pro Super Thermo capsules. All lots and sizes distributed since November 2012
- OxyElite Pro Ultra-Intense Thermo Advanced Formula capsules. All lots and sizes distributed since July 2013
- OxyElite Pro Super Thermo Powder Plus Advanced Carnitine Transport System (all flavors). All lots and sizes distributed since November 2012

If you do not voluntarily cease distribution and conduct a recall, FDA may, by order, require you to immediately cease distribution of these dietary supplements and also may require you to immediately give notice to other parties. If you elect to take the action requested in this letter, you should do so within the time frame and in the manner described below under "Opportunity to Initiate a Voluntary Recall" to avoid further regulatory action by FDA concerning the dietary supplements listed above.

Basis for FDA's Determination

The basis for FDA's determination that there is a reasonable probability that the above-listed OxyElite Pro products are adulterated under sections 402(f)(1)(A) and (B) of the FD&C Act and that there is a reasonable probability that the use of or exposure to these dietary supplements will cause serious adverse health consequences or death to humans is as follows:

On September 24, 2013, the FDA District Office in San Francisco (SAN-DO) notified FDA's Office of Foods and Veterinary Medicine's (OFVM) Coordinated Outbreak Response and Evaluation Network (CORE) of seven Hawaii residents with acute liver failure/non-viral hepatitis. Information obtained by local public health authorities from interviews with these patients, from their health care providers, and from their medical records revealed that the patients had consumed OxyElite Pro before becoming ill. Although some patients reported using multiple products, OxyElite Pro was determined to be the only common exposure among them, according to the Hawaii Department of Health (HDOH) and the Centers for Disease Control and Prevention (CDC), which initiated a joint investigation. The patients were reported to have taken OxyElite Pro for weight loss or to accompany exercise regimens. Since the initial report, HDOH and CDC have identified additional cases of liver disease in Hawaii, and cases have also been reported in other states and the District of Columbia. Among case-patients identified in Hawaii and elsewhere who have taken OxyElite Pro, consumption of the capsule form, and less commonly the powder form, has been reported prior to illness onset.

USPlabs reformulated its OxyElite Pro line of dietary supplements in November 2012 to remove 1,3-dimethylamylamine, commonly known as DMAA. According to their labels, all of the new OxyElite Pro formulations contain aegeline (also referred to as N-[2-hydroxy-2(4-methoxyphenyl) ethyl]-3-phenyl-2-propenamide), which is declared as a dietary ingredient in the Supplement Facts panel. The products listed above are labeled to contain other dietary ingredients in addition to aegeline, but these vary by product. As explained below and in FDA's Warning Letter to your firm, dated October 11, 2013, the presence of aegeline in these products causes them to be adulterated under section 402(f)(1)(B) of the FD&C Act because aegeline is a new dietary

ingredient for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury.

Adverse Event Reports

As of October 26, 2013, the Center for Food Safety and Applied Nutrition (CFSAN) had received 46 medical records of Hawaii residents with liver disease. Of the 46 patients, 40 (87%) fulfilled criteria established by HDOH and CDC to be considered a case of liver damage following consumption of a dietary supplement. These inclusion criteria are listed in the CDC's Morbidity and Mortality Weekly Report (MMWR) dated October 11, 2013, in an article entitled *Notes from the Field: Acute Hepatitis and Liver Failure Following the Use of a Dietary Supplement Intended for Weight Loss or Muscle Building — May–October 2013,* which can be found at: http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6240a1.htm?s_cid=mm6240a1_w. Of the 40 patients who fulfilled case criteria, 27 (68%) reported taking OxyElite Pro before becoming ill. The 13 remaining patients reported taking various other dietary supplements (e.g., green tea powder, creatine, protein shakes sold as dietary supplements, VERSA-1, and Hydroxycut.)

The following findings pertain to the 27 Hawaii residents who meet the case definition and had consumed OxyElite Pro before becoming ill. Patients ranged in age from 16 – 54 years; most were previously healthy and none had a history of liver disease. Sixteen (59%) were female, and 18 (67%) were reported as Asian/Pacific Islander/Native Hawaiian. The patients resided on all of the major islands of Hawaii and obtained the product from different sources. Seventeen (63%) patients reported taking OxyElite Pro as the sole dietary supplement; 9 (33%) took OxyElite Pro along with one or more other supplements; and one patient consumed OxyElite Pro along with a prescription weight loss drug. The duration of OxyElite Pro use prior to illness onset ranged from 1 month to 2 years. Records indicate the patients used OxyElite Pro according to the manufacturer's recommended dose and frequency of use. Although most of the medical records did not specify which version of OxyElite Pro was taken, in 5 medical records there was specific mention that the patients consumed one of the new formulations of OxyElite Pro before becoming ill.

Nine of the patients underwent liver biopsy. Pathologic descriptions of the biopsies most often mentioned "hepatocellular necrosis" (in one patient, 50% of the liver was necrosed) and "acute active hepatitis," often with cholestatic features. Pathologists most often summarized the findings of liver biopsy as "consistent with drug/toxin-injury." In approximately 75% of the 27 cases, attending physicians concluded that ingestion of OxyElite Pro was the most likely cause of pathology.

Among the 27 patients, one died of fulminant liver failure, one surviving patient received a liver transplant, and two additional patients were awaiting liver transplants at the time of record review. Among other patients, liver function tests demonstrated a gradual return to normal after the patient stopped taking OxyElite Pro.

One of the patients began using OxyElite Pro in March 2013 and sought health care in June 2013 for two weeks of fatigue, poor appetite, diarrhea, and jaundice. Symptoms resolved upon discontinuation of OxyElite Pro. Two months later, the patient resumed taking OxyElite Pro and the symptoms reappeared within weeks, prompting multiple emergency department visits. Laboratory tests performed during these visits showed elevated liver enzymes and bilirubin, and the health care provider's diagnosis was "hepatitis due to OxyElite [Pro] exposure."

The 27 patients underwent extensive evaluation for known infectious and non-infectious causes of liver disease. Infectious causes that were ruled out after testing include: hepatitis A, B, C, and E; cytomegalovirus (CMV), Epstein Barr virus (EBV), herpes simplex virus (HSV), varicella-zoster virus (VZV), and *Leptospira*. Tests also ruled out the following non-infectious causes: auto-immune hepatitis, Wilson's disease, hemochromatosis, and alpha-1-antitrypsin deficiency. Alcoholic liver disease or acetaminophen ingestion were also ruled out.

As of October 26, 2013, HDOH had identified 35 persons who suffered liver damage after taking OxyElite Pro (this number includes the 27 patients whose records have been obtained and reviewed by FDA). Of these 35 cases, 21 (60%) used only OxyElite Pro and 14 (40%) consumed OxyElite Pro along with one or more other dietary supplements. Among the Hawaii patients with available information, only 15% had taken OxyElite Pro prior to 2013; 55% did not begin using the product until after May 1, 2013. Thirty-two (91%) of the 35 patients are known to have consumed one of the new formulations of OxyElite Pro.

Since identification of the illnesses in Hawaii, FDA and CDC have identified patients in ten other states as of November 6, 2013, with liver disease that developed after consuming OxyElite Pro. Information on these patients is being collected and evaluated by FDA, CDC, and our state partners.

Link to New Formulation OxyElite Pro Products

These findings strongly suggest that the new formulations of OxyElite Pro are responsible for this outbreak of serious liver damage. The evidence includes:

- Most of the patients were previously healthy and it is unlikely they would have developed liver disease absent the ingestion of OxyElite Pro.
- Viral, autoimmune, prescription drug, alcohol, and over-the-counter drugs were ruled out as alternative causes of illness.
- Medical records indicate that attending physicians considered OxyElite Pro to be the likely cause of illness in approximately 75% of the cases FDA reviewed.
- There was a strong temporal relationship between the date when patients began to take OxyElite Pro and development of liver abnormalities.
- There was a temporal relationship between the date when USPlabs began production of the new formulations of OxyElite Pro and the development of liver abnormalities in patients taking OxyElite Pro.
- Discontinuation of OxyElite Pro led to the reversal of liver disease (including return to normal liver function) in surviving patients whose liver damage was not severe enough to require liver transplantation.
- Signs and symptoms of hepatitis recurred in one patient after resuming the use of OxyElite Pro.
- Cases of liver toxicity were recognized within months of the start of distribution of the new formulations of OxyElite Pro; in cases where information about the formulation used was collected, records confirm that patients were using one of the new formulations.
- Among Hawaii patients with available information, most began taking OxyElite Pro only after USPlabs had destroyed remaining stocks of the old formulation containing DMAA. Further, 91% of these patients are known to have consumed one of the new formulations of OxyElite Pro.

There is a Reasonable Probability that the OxyElite Pro Products are Adulterated under Section 402(f)(1)(A) of the FD&C Act

Based on the results of the epidemiological investigation described above, FDA concludes that there is a reasonable probability that the OxyElite Pro products are adulterated under section 402(f)(1)(A)(i) of the FD&C Act (21 U.S.C. § 342(f)(1)(A)(i)) because they present a significant or unreasonable risk of illness or injury under the conditions of use recommended or suggested in the labeling. This conclusion is based on epidemiological evidence showing that use of the OxyElite Pro products has been associated with serious adverse health consequences, namely serious liver damage leading to hospitalization, liver failure necessitating transplant, and death. The introduction of adulterated dietary supplements into interstate commerce is prohibited under section 301(a) of the FD&C Act (21 U.S.C. 331(a)).

There is a Reasonable Probability that the OxyElite Pro Products Are Adulterated under Sections 402(f)(1)(B) and 413(a) of the FD&C Act

Based on the information available to FDA, aegeline was not lawfully marketed as a dietary ingredient in the United States before October 15, 1994, and aegeline has not been present in the food supply as an article used for food in a form in which the food has not been chemically altered. Therefore, aegeline is subject to the notification requirement in section 413(a)(2) of the FD&C Act (21 U.S.C. 350b(a)(2)) and 21 CFR 190.6. Your firm did not submit the required notification to FDA. For this reason, FDA stated in its October 11, 2013, Warning Letter that the OxyElite Pro products containing aegeline are adulterated under sections 402(f)(1)(B) and 413(a) of the FD&C Act. The introduction of dietary supplements that are adulterated under section 413 of the FD&C Act into interstate commerce is prohibited under sections 301(a) and (v) of the FD&C Act (21 U.S.C. 331(a) and (v)).

The same facts and reasoning supporting FDA's assertion in the Warning Letter that the OxyElite Pro products are adulterated under sections 402(f)(1)(B) and 413(a) of the FD&C Act because your firm did not submit the required notification to FDA also support a determination that there is a reasonable probability that these products are adulterated under the same provisions of the FD&C Act.

There is a Reasonable Probability that Use of the OxyElite Pro Products Will Cause Serious Adverse Health Consequences or Death to Humans

In light of the epidemiological evidence outlined above, FDA concludes that there is a reasonable probability that the use of the OxyElite Pro products will cause serious adverse health consequences or death to humans. The OxyElite Pro products have been associated with liver damage resulting, in some instances, in serious adverse health consequences that have included hospitalization, liver failure necessitating a liver transplant, and, in the case of one patient, death.

Agency Determinations

Based upon the results of the epidemiological investigation described above, FDA has determined that there is a reasonable probability that the new formulations of OxyElite Pro manufactured after November 2012 are adulterated under sections 402(f)(l)(A) of the FD&C Act and that there is a reasonable probability that the use of or exposure to these products will cause serious adverse

health consequences or death to humans. Further, FDA has determined that there is a reasonable probability that these OxyElite Pro products are adulterated under sections 402(f)(1)(B) and 413(a) of the FD&C Act because they contain aegeline, a new dietary ingredient for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury.

Opportunity to Initiate a Voluntary Recall

As discussed above, in accordance with section 423(a) of the FD&C Act, we are providing you with an opportunity to voluntarily cease distribution and conduct a recall of the referenced dietary supplements. If you elect to voluntarily cease distribution and conduct a recall of these products, you should do so in the following time and manner:

- Within two (2) business days of your receipt of this letter, cease distribution and initiate a recall of the following products:

  OxyElite Pro Super Thermo capsules. All lots and sizes distributed since November 2012

  OxyElite Pro Ultra-Intense Thermo Advanced Formula capsules. All lots and sizes distributed since July 2013

  OxyElite Pro Super Thermo Powder Plus Advanced Carnitine Transport System (all flavors). All lots and sizes distributed since November 2012

  Notify all direct consignees and request that those who further distributed these products conduct a sub-recall to the consumer level.

- Conduct your recall(s) of these products in coordination with the FDA Dallas District Recall Coordinator.

- Follow the procedures for recalls found in FDA's regulations at 21 CFR Part 7 to the extent appropriate. A copy of these regulations is enclosed.

If you do not voluntarily cease distribution and conduct a recall in the time and manner described in this section, FDA may, by order, require you to immediately cease distribution of the referenced dietary supplements. Additionally, FDA may, by order, require you to immediately notify all persons manufacturing, processing, packing, transporting, distributing, receiving, holding, or importing and selling these dietary supplements to immediately cease distribution of such articles; and to immediately notify all persons to which these dietary supplements have been distributed, transported, or sold, to immediately cease further distribution.

Please respond to this letter by contacting Mr. Reynaldo R. Rodriguez, Jr., Dallas District Director, at telephone number (214) 253-5201 or via email at reynaldo.rodriguez@fda.hhs.gov as soon as possible. If a response is not received from you within two (2) business days of your receipt of this

letter, FDA may, by order, require you to immediately cease distribution and notify applicable parties, as explained above.

Sincerely,

Michael R. Taylor
Deputy Commissioner for Foods
and Veterinary Medicine

Enclosure: 21 CFR Part 7

AUTHENTICATED U.S. GOVERNMENT INFORMATION GPO

§5.1105 Chief Counsel, Food and Drug Administration.

The Office of the Chief Counsel's mailing address is White Oak Bldg. 1, 10903 New Hampshire Ave., Silver Spring, MD 20993.

§5.1110 FDA public information offices.

(a) *Division of Dockets Management.* The Division of Dockets Management public room is located in rm. 1061, 5630 Fishers Lane, Rockville, MD 20852, Telephone: 301–827–6860.

(b) *Division of Freedom of Information.* The Division of Freedom of Information public room is located in rm. 1050, Element Bldg., 12420 Parklawn Dr., Rockville, MD 20857, Telephone: 301–796–3900.

(c) *Press Relations Staff.* Press offices are located in White Oak Bldg. 1, 10903 New Hampshire Ave., Silver Spring, MD 20993, Telephone: 301–827–6242; and at 5100 Paint Branch Pkwy., College Park, MD 20740, Telephone: 301–436–2335.

PART 7—ENFORCEMENT POLICY

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AUTHORITY: 21 U.S.C. 321–393; 42 U.S.C. 241, 262, 263b–263n, 264.

SOURCE: 42 FR 15567, Mar. 22, 1977, unless otherwise noted.

Subpart A—General Provisions

§7.1 Scope.

This part governs the practices and procedures applicable to regulatory enforcement actions initiated by the Food and Drug Administration pursuant to the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*) and other laws that it administers. This part also provides guidance for manufacturers and distributors to follow with respect to their voluntary removal or correction of marketed violative products. This part is promulgated to clarify and explain the regulatory practices and procedures of the Food and Drug Administration, enhance public understanding, improve consumer protection, and assure uniform and consistent application of practices and procedures throughout the agency.

[43 FR 26218, June 16, 1978, as amended at 65 FR 56476, Sept. 19, 2000]

§7.3 Definitions.

(a) *Agency* means the Food and Drug Administration.

(b) *Citation* or *cite* means a document and any attachments thereto that provide notice to a person against whom criminal prosecution is contemplated of the opportunity to present views to the agency regarding an alleged violation.

(c) *Respondent* means a person named in a notice who presents views concerning an alleged violation either in person, by designated representative, or in writing.

(d) *Responsible individual* includes those in positions of power or authority to detect, prevent, or correct violations of the Federal Food, Drug, and Cosmetic Act.

(e) [Reserved]

(f) *Product* means an article subject to the jurisdiction of the Food and Drug Administration, including any

food, drug, and device intended for human or animal use, any cosmetic and biologic intended for human use, any tobacco product intended for human use, and any item subject to a quarantine regulation under part 1240 of this chapter. *Product* does not include an electronic product that emits radiation and is subject to parts 1003 and 1004 of this chapter.

(g) *Recall* means a firm's removal or correction of a marketed product that the Food and Drug Administration considers to be in violation of the laws it administers and against which the agency would initiate legal action, e.g., seizure. *Recall* does not include a market withdrawal or a stock recovery.

(h) *Correction* means repair, modification, adjustment, relabeling, destruction, or inspection (including patient monitoring) of a product without its physical removal to some other location.

(i) *Recalling firm* means the firm that initiates a recall or, in the case of a Food and Drug Administration-requested recall, the firm that has primary responsibility for the manufacture and marketing of the product to be recalled.

(j) *Market withdrawal* means a firm's removal or correction of a distributed product which involves a minor violation that would not be subject to legal action by the Food and Drug Administration or which involves no violation, e.g., normal stock rotation practices, routine equipment adjustments and repairs, etc.

(k) *Stock recovery* means a firm's removal or correction of a product that has not been marketed or that has not left the direct control of the firm, i.e., the product is located on premises owned by, or under the control of, the firm and no portion of the lot has been released for sale or use.

(l) *Recall strategy* means a planned specific course of action to be taken in conducting a specific recall, which addresses the depth of recall, need for public warnings, and extent of effectiveness checks for the recall.

(m) *Recall classification* means the numerical designation, i.e., I, II, or III, assigned by the Food and Drug Administration to a particular product recall to indicate the relative degree of health hazard presented by the product being recalled.

(1) Class I is a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death.

(2) Class II is a situation in which use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.

(3) Class III is a situation in which use of, or exposure to, a violative product is not likely to cause adverse health consequences.

(n) *Consignee* means anyone who received, purchased, or used the product being recalled.

[42 FR 15567, Mar. 22, 1977, as amended at 43 FR 26218, June 16, 1978; 44 FR 12167, Mar. 6, 1979; 77 FR 5176, Feb. 2, 2012]

§ 7.12 Guaranty.

In case of the giving of a guaranty or undertaking referred to in section 303(c)(2) or (3) of the act, each person signing such guaranty or undertaking shall be considered to have given it.

§ 7.13 Suggested forms of guaranty.

(a) A guaranty or undertaking referred to in section 303(c)(2) of the act may be:

(1) Limited to a specific shipment or other delivery of an article, in which case it may be a part of or attached to the invoice or bill of sale covering such shipment or delivery, or

(2) General and continuing, in which case, in its application to any shipment or other delivery of an article, it shall be considered to have been given at the date such article was shipped or delivered by the person who gives the guaranty or undertaking.

(b) The following are suggested forms of guaranty or undertaking under section 303(c)(2) of the act:

(1) Limited form for use on invoice or bill of sale.

(Name of person giving the guaranty or undertaking) hereby guarantees that no article listed herein is adulterated or misbranded within the meaning of the Federal Food, Drug, and Cosmetic Act, or is an article

which may not, under the provisions of section 404, 505, or 512 of the act, be introduced into interstate commerce.

(Signature and post-office address of person giving the guaranty or undertaking.)

(2) General and continuing form.

The article comprising each shipment or other delivery hereafter made by (name of person giving the guaranty or undertaking) to, or in the order of (name and post-office address of person to whom the guaranty or undertaking is given) is hereby guaranteed, as of the date of such shipment or delivery, to be, on such date, not adulterated or misbranded within the meaning of the Federal Food, Drug, and Cosmetic Act, and not an article which may not, under the provisions of section 404, 505, or 512 of the act, be introduced into interstate commerce.

(Signature and post-office address of person giving the guaranty of undertaking.)

(c) The application of a guaranty or undertaking referred to in section 303(c)(2) of the act to any shipment or other delivery of an article shall expire when such article, after shipment or delivery by the person who gave such guaranty or undertaking, becomes adulterated or misbranded within the meaning of the act, or becomes an article which may not, under the provisions of section 404, 505, or 512 of the act, be introduced into interstate commerce.

(d) A guaranty or undertaking referred to in section 303(c)(3) of the act shall state that the shipment or other delivery of the color additive covered thereby was manufactured by a signer thereof. It may be a part of or attached to the invoice or bill of sale covering such color. If such shipment or delivery is from a foreign manufacturer, such guaranty or undertaking shall be signed by such manufacturer and by an agent of such manufacturer who resides in the United States.

(e) The following are suggested forms of guaranty or undertaking under section 303(c)(3) of the act:

(1) For domestic manufacturers:

(Name of manufacturer) hereby guarantees that all color additives listed herein were manufactured by him, and (where color additive regulations require certification) are from batches certified in accordance with the applicable regulations promulgated under the Federal Food, Drug, and Cosmetic Act.

(Signature and post-office address of manufacturer.)

(2) For foreign manufacturers:

(Name of manufacturer and agent) hereby severally guarantee that all color additives listed herein were manufactured by (name of manufacturer), and (where color additive regulations require certification) are from batches certified in accordance with the applicable regulations promulgated under the Federal Food, Drug, and Cosmetic Act.

(Signature and post-office address of manufacturer.)

(Signature and post-office address of agent.)

(f) For the purpose of a guaranty or undertaking under section 303(c)(3) of the act the manufacturer of a shipment or other delivery of a color additive is the person who packaged such color.

(g) A guaranty or undertaking, if signed by two or more persons, shall state that such persons severally guarantee the article to which it applies.

(h) No representation or suggestion that an article is guaranteed under the act shall be made in labeling.

Subpart B [Reserved]

Subpart C—Recalls (Including Product Corrections)—Guidance on Policy, Procedures, and Industry Responsibilities

SOURCE: 43 FR 26218, June 16, 1978, unless otherwise noted.

§ 7.40 Recall policy.

(a) Recall is an effective method of removing or correcting consumer products that are in violation of laws administered by the Food and Drug Administration. Recall is a voluntary action that takes place because manufacturers and distributors carry out their responsibility to protect the public health and well-being from products that present a risk of injury or gross deception or are otherwise defective. This section and §§ 7.41 through 7.59 recognize the voluntary nature of recall by providing guidance so that responsible firms may effectively discharge their recall responsibilities. These sections also recognize that recall is an alternative to a Food and Drug Administration-initiated court action for removing or correcting violative, distributed products by setting forth specific recall procedures for the Food and

Drug Administration to monitor recalls and assess the adequacy of a firm's efforts in recall.

(b) Recall may be undertaken voluntarily and at any time by manufacturers and distributors, or at the request of the Food and Drug Administration. A request by the Food and Drug Administration that a firm recall a product is reserved for urgent situations and is to be directed to the firm that has primary responsibility for the manufacture and marketing of the product that is to be recalled.

(c) Recall is generally more appropriate and affords better protection for consumers than seizure, when many lots of product have been widely distributed. Seizure, multiple seizure, or other court action is indicated when a firm refuses to undertake a recall requested by the Food and Drug Administration, or where the agency has reason to believe that a recall would not be effective, determines that a recall is ineffective, or discovers that a violation is continuing.

[43 FR 26218, June 16, 1978, as amended at 65 FR 56476, Sept. 19, 2000]

§ 7.41 Health hazard evaluation and recall classification.

(a) An evaluation of the health hazard presented by a product being recalled or considered for recall will be conducted by an ad hoc committee of Food and Drug Administration scientists and will take into account, but need not be limited to, the following factors:

(1) Whether any disease or injuries have already occurred from the use of the product.

(2) Whether any existing conditions could contribute to a clinical situation that could expose humans or animals to a health hazard. Any conclusion shall be supported as completely as possible by scientific documentation and/or statements that the conclusion is the opinion of the individual(s) making the health hazard determination.

(3) Assessment of hazard to various segments of the population, e.g., children, surgical patients, pets, livestock, etc., who are expected to be exposed to the product being considered, with particular attention paid to the hazard to those individuals who may be at greatest risk.

(4) Assessment of the degree of seriousness of the health hazard to which the populations at risk would be exposed.

(5) Assessment of the likelihood of occurrence of the hazard.

(6) Assessment of the consequences (immediate or long-range) of occurrence of the hazard.

(b) On the basis of this determination, the Food and Drug Administration will assign the recall a classification, i.e., Class I, Class II, or Class III, to indicate the relative degree of health hazard of the product being recalled or considered for recall.

§ 7.42 Recall strategy.

(a) *General.* (1) A recall strategy that takes into account the following factors will be developed by the agency for a Food and Drug Administration-requested recall and by the recalling firm for a firm-initiated recall to suit the individual circumstances of the particular recall:

(i) Results of health hazard evaluation.

(ii) Ease in identifying the product.

(iii) Degree to which the product's deficiency is obvious to the consumer or user.

(iv) Degree to which the product remains unused in the market-place.

(v) Continued availability of essential products.

(2) The Food and Drug Administration will review the adequacy of a proposed recall strategy developed by a recalling firm and recommend changes as appropriate. A recalling firm should conduct the recall in accordance with an approved recall strategy but need not delay initiation of a recall pending review of its recall strategy.

(b) *Elements of a recall strategy.* A recall strategy will address the following elements regarding the conduct of the recall:

(1) *Depth of recall.* Depending on the product's degree of hazard and extent of distribution, the recall strategy will specify the level in the distribution chain to which the recall is to extend, as follows:

(i) Consumer or user level, which may vary with product, including any

intermediate wholesale or retail level; or

(ii) Retail level, including any intermediate wholesale level; or

(iii) Wholesale level.

(2) *Public warning.* The purpose of a public warning is to alert the public that a product being recalled presents a serious hazard to health. It is reserved for urgent situations where other means for preventing use of the recalled product appear inadequate. The Food and Drug Administration in consultation with the recalling firm will ordinarily issue such publicity. The recalling firm that decides to issue its own public warning is requested to submit its proposed public warning and plan for distribution of the warning for review and comment by the Food and Drug Administration. The recall strategy will specify whether a public warning is needed and whether it will issue as:

(i) General public warning through the general news media, either national or local as appropriate, or

(ii) Public warning through specialized news media, e.g., professional or trade press, or to specific segments of the population such as physicians, hospitals, etc.

(3) *Effectiveness checks.* The purpose of effectiveness checks is to verify that all consignees at the recall depth specified by the strategy have received notification about the recall and have taken appropriate action. The method for contacting consignees may be accomplished by personal visits, telephone calls, letters, or a combination thereof. A guide entitled "Methods for Conducting Recall Effectiveness Checks" that describes the use of these different methods is available upon request from the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. The recalling firm will ordinarily be responsible for conducting effectiveness checks, but the Food and Drug Administration will assist in this task where necessary and appropriate. The recall strategy will specify the method(s) to be used for and the level of effectiveness checks that will be conducted, as follows:

(i) Level A—100 percent of the total number of consignees to be contacted;

(ii) Level B—Some percentage of the total number of consignees to be contacted, which percentage is to be determined on a case-by-case basis, but is greater that 10 percent and less than 100 percent of the total number of consignees;

(iii) Level C—10 percent of the total number of consignees to be contacted;

(iv) Level D—2 percent of the total number of consignees to be contacted; or

(v) Level E—No effectiveness checks.

[43 FR 26218, June 16, 1978, as amended at 46 FR 8455, Jan. 27, 1981; 59 FR 14363, Mar. 28, 1994; 68 FR 24879, May 9, 2003]

§ 7.45 Food and Drug Administration-requested recall.

(a) The Commissioner of Food and Drugs or designee may request a firm to initiate a recall when the following determinations have been made:

(1) That a product that has been distributed presents a risk of illness or injury or gross consumer deception.

(2) That the firm has not initiated a recall of the product.

(3) That an agency action is necessary to protect the public health and welfare.

(b) The Commissioner or his designee will notify the firm of this determination and of the need to begin immediately a recall of the product. Such notification will be by letter or telegram to a responsible official of the firm, but may be preceded by oral communication or by a visit from an authorized representative of the local Food and Drug Administration district office, with formal, written confirmation from the Commissioner or his designee afterward. The notification will specify the violation, the health hazard classification of the violative product, the recall strategy, and other appropriate instructions for conducting the recall.

(c) Upon receipt of a request to recall, the firm may be asked to provide the Food and Drug Administration any or all of the information listed in § 7.46(a). The firm, upon agreeing to the recall request, may also provide other information relevant to the agency's

determination of the need for the recall or how the recall should be conducted.

[43 FR 26218, June 16, 1978, as amended at 69 FR 17290, Apr. 2, 2004]

§ 7.46 Firm-initiated recall.

(a) A firm may decide of its own volition and under any circumstances to remove or correct a distributed product. A firm that does so because it believes the product to be violative is requested to notify immediately the appropriate Food and Drug Administration district office listed in § 5.115 of this chapter. Such removal or correction will be considered a recall only if the Food and Drug Administration regards the product as involving a violation that is subject to legal action, e.g., seizure. In such cases, the firm will be asked to provide the Food and Drug Administration the following information:

(1) Identity of the product involved.

(2) Reason for the removal or correction and the date and circumstances under which the product deficiency or possible deficiency was discovered.

(3) Evaluation of the risk associated with the deficiency or possible deficiency.

(4) Total amount of such products produced and/or the timespan of the production.

(5) Total amount of such products estimated to be in distribution channels.

(6) Distribution information, including the number of direct accounts and, where necessary, the identity of the direct accounts.

(7) A copy of the firm's recall communication if any has issued, or a proposed communication if none has issued.

(8) Proposed strategy for conducting the recall.

(9) Name and telephone number of the firm official who should be contacted concerning the recall.

(b) The Food and Drug Administration will review the information submitted, advise the firm of the assigned recall classification, recommend any appropriate changes in the firm's strategy for the recall, and advise the firm that its recall will be placed in the weekly FDA Enforcement Report. Pending this review, the firm need not delay initiation of its product removal or correction.

(c) A firm may decide to recall a product when informed by the Food and Drug Administration that the agency has determined that the product in question violates the law, but the agency has not specifically requested a recall. The firm's action also is considered a firm-initiated recall and is subject to paragraphs (a) and (b) of this section.

(d) A firm that initiates a removal or correction of its product which the firm believes is a market withdrawal should consult with the appropriate Food and Drug Administration district office when the reason for the removal or correction is not obvious or clearly understood but where it is apparent, e.g., because of complaints or adverse reactions regarding the product, that the product is deficient in some respect. In such cases, the Food and Drug Administration will assist the firm in determining the exact nature of the problem.

§ 7.49 Recall communications.

(a) *General.* A recalling firm is responsible for promptly notifying each of its affected direct accounts about the recall. The format, content, and extent of a recall communication should be commensurate with the hazard of the product being recalled and the strategy developed for that recall. In general terms, the purpose of a recall communication is to convey:

(1) That the product in question is subject to a recall.

(2) That further distribution or use of any remaining product should cease immediately.

(3) Where appropriate, that the direct account should in turn notify its customers who received the product about the recall.

(4) Instructions regarding what to do with the product.

(b) *Implementation.* A recall communication can be accomplished by telegrams, mailgrams, or first class letters conspicuously marked, preferably in bold red type, on the letter and the envelope: "DRUG [or FOOD, BIOLOGIC, etc.] RECALL [or CORRECTION]". The letter and the envelope should be also marked: "URGENT" for class I and class

II recalls and, when appropriate, for class III recalls. Telephone calls or other personal contacts should ordinarily be confirmed by one of the above methods and/or documented in an appropriate manner.

(c) *Contents.* (1) A recall communication should be written in accordance with the following guidelines:

(i) Be brief and to the point;

(ii) Identify clearly the product, size, lot number(s), code(s) or serial number(s) and any other pertinent descriptive information to enable accurate and immediate identification of the product;

(iii) Explain concisely the reason for the recall and the hazard involved, if any;

(iv) Provide specific instructions on what should be done with respect to the recalled products; and

(v) Provide a ready means for the recipient of the communication to report to the recalling firm whether it has any of the product, e.g., by sending a postage-paid, self-addressed postcard or by allowing the recipient to place a collect call to the recalling firm.

(2) The recall communication should not contain irrelevant qualifications, promotional materials, or any other statement that may detract from the message. Where necessary, followup communications should be sent to those who fail to respond to the initial recall communication.

(d) *Responsibility of recipient.* Consignees that receive a recall communication should immediately carry out the instructions set forth by the recalling firm and, where necessary, extend the recall to its consignees in accordance with paragraphs (b) and (c) of this section.

§ 7.50 Public notification of recall.

The Food and Drug Administration will promptly make available to the public in the weekly FDA Enforcement Report a descriptive listing of each new recall according to its classification, whether it was Food and Drug Administration-requested or firm-initiated, and the specific action being taken by the recalling firm. The Food and Drug Administration will intentionally delay public notification of recalls of certain drugs and devices where the agency determines that public notification may cause unnecessary and harmful anxiety in patients and that initial consultation between patients and their physicians is essential. The report will not include a firm's product removals or corrections which the agency determines to be market withdrawals or stock recoveries. The report, which also includes other Food and Drug Administration regulatory actions, e.g., seizures that were effected and injunctions and prosecutions that were filed, is available upon request from the Office of Public Affairs (HFI–1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

§ 7.53 Recall status reports.

(a) The recalling firm is requested to submit periodic recall status reports to the appropriate Food and Drug Administration district office so that the agency may assess the progress of the recall. The frequency of such reports will be determined by the relative urgency of the recall and will be specified by the Food and Drug Administration in each recall case; generally the reporting interval will be between 2 and 4 weeks.

(b) Unless otherwise specified or inappropriate in a given recall case, the recall status report should contain the following information:

(1) Number of consignees notified of the recall, and date and method of notification.

(2) Number of consignees responding to the recall communication and quatity of products on hand at the time it was received.

(3) Number of consignees that did not respond (if needed, the identity of nonresponding consignees may be requested by the Food and Drug Administration).

(4) Number of products returned or corrected by each consignee contacted and the quantity of products accounted for.

(5) Number and results of effectiveness checks that were made.

(6) Estimated time frames for completion of the recall.

(c) Recall status reports are to be discontinued when the recall is terminated by the Food and Drug Administration.

§ 7.55 Termination of a recall.

(a) A recall will be terminated when the Food and Drug Administration determines that all reasonable efforts have been made to remove or correct the product in accordance with the recall strategy, and when it is reasonable to assume that the product subject to the recall has been removed and proper disposition or correction has been made commensurate with the degree of hazard of the recalled product. Written notification that a recall is terminated will be issued by the appropriate Food and Drug Administration district office to the recalling firm.

(b) A recalling firm may request termination of its recall by submitting a written request to the appropriate Food and Drug Adminstration district office stating that the recall is effective in accordance with the criteria set forth in paragraph (a) of this section, and by accompanying the request with the most current recall status report and a description of the disposition of the recalled product.

§ 7.59 General industry guidance.

A recall can be disruptive of a firm's operation and business, but there are several steps a prudent firm can take in advance to minimize this disruptive effect. Notwithstanding similar specific requirements for certain products in other parts of this chapter, the following is provided by the Food and Drug Administration as guidance for a firm's consideration:

(a) Prepare and maintain a current written contingency plan for use in initiating and effecting a recall in accordance with §§7.40 through 7.49, 7.53, and 7.55.

(b) Use sufficient coding of regulated products to make possible positive lot identification and to facilitate effective recall of all violative lots.

(c) Maintain such product distribution records as are necessary to facilitate location of products that are being recalled. Such records should be maintained for a period of time that exceeds the shelf life and expected use of the product and is at least the length of time specified in other applicable regulations concerning records retention.

Subpart D [Reserved]

Subpart E—Criminal Violations

§ 7.84 Opportunity for presentation of views before report of criminal violation.

(a)(1) Except as provided in paragraph (a) (2) and (3) of this section, a person against whom criminal prosecution under the Federal Food, Drug, and Cosmetic Act is contemplated by the Commissioner of Food and Drugs shall be given appropriate notice and an opportunity to present information and views to show cause why criminal prosecution should not be recommended to a United States attorney.

(2) Notice and opportunity need not be provided if the Commissioner has reason to believe that they may result in the alteration or destruction of evidence or in the prospective defendant's fleeing to avoid prosecution.

(3) Notice and opportunity need not be provided if the Commissioner contemplates recommending further investigation by the Department of Justice.

(b) If a statute enforced by the Commissioner does not contain a provision for an opportunity to present views, the Commissioner need not, but may in the Commissioner's discretion, provide notice and an opportunity to present views.

(c) If an apparent violation of the Federal Food, Drug, and Cosmetic Act also constitutes a violation of any other Federal statute(s), and the Commissioner contemplates recommending prosecution under such other statute(s) as well, the notice of opportunity to present views will include all violations.

(d) Notice of an opportunity to present views may be by letter, standard form, or other document(s) identifying the products and/or conduct alleged to violate the law. The notice shall—

(1) Be sent by registered or certified mail, telegram, telex, personal delivery, or any other appropriate mode of written communication;

(2) Specify the time and place where those named may present their views;

(3) Summarize the violations that constitute the basis of the contemplated prosecution;

(4) Describe the purpose and procedure of the presentation; and

(5) Furnish a form on which the legal status of any person named in the notice may be designated.

(e) If more than one person is named in a notice, a separate opportunity for presentation of views shall be scheduled on request. Otherwise, the time and place specified in a notice may be changed only upon a showing of reasonable grounds. A request for any change shall be addressed to the Food and Drug Administration office that issued the notice and shall be received in that office at least 3 working days before the date set in the notice.

(f) A person who has received a notice is under no legal obligation to appear or answer in any manner. A person choosing to respond may appear personally, with or without a representative, or may designate a representative to appear for him or her. Alternatively, a person may respond in writing. If a person elects not to respond on or before the time scheduled, the Commissioner will, without further notice, decide whether to recommend criminal prosecution to a United States attorney on the basis of the information available.

(g) If a respondent chooses to appear solely by designated representative, that representative shall present a signed statement of authorization. If a representative appears for more than one respondent, the representative shall submit independent documentation of authority to act for each respondent. If a representative appears without written authorization, the opportunity to present views with respect to that respondent may be provided at that time only if the authenticity of the representative's authority is first verified by telephone or other appropriate means.

[44 FR 12167, Mar. 6, 1979]

§ 7.85 Conduct of a presentation of views before report of criminal violation.

(a) The presentation of views shall be heard by a designated Food and Drug Administration employee. Other Food and Drug Administration employees may be present.

(b) A presentation of views shall not be open to the public. The agency employee designated to receive views will permit participation of other persons only if they appear with the respondent or the respondent's designated representative, and at the request of, and on behalf of, the respondent.

(c) A respondent may present any information of any kind bearing on the Commissioner's determination to recommend prosecution. Information may include statements of persons appearing on the respondent's behalf, letters, documents, laboratory analyses, if applicable, or other relevant information or arguments. The opportunity to present views shall be informal. The rules of evidence shall not apply. Any information given by a respondent, including statements by the respondent, shall become part of the agency's records concerning the matter and may be used for any official purpose. The Food and Drug Administration is under no obligation to present evidence or witnesses.

(d) If the respondent holds a "guaranty or undertaking" as described in section 303(c) of the act (21 U.S.C. 333(c)) that is applicable to the notice, that document, or a verified copy of it, may be presented by the respondent.

(e) A respondent may have an oral presentation recorded and transcribed at his or her expense, in which case a copy of the transcription shall be furnished to the Food and Drug Administration office from which the notice issued. The employee designated to receive views may order a presentation of views recorded and transcribed at agency expense, in which case a copy of such transcription shall be provided to each respondent.

(f) If an oral presentation is not recorded and transcribed, the agency employee designated to receive views shall dictate a written summary of the presentation. A copy of the summary shall be provided to each respondent.

(g) A respondent may comment on the summary or may supplement any response by additional written or documentary evidence. Any comment or addition shall be furnished to the Food and Drug Administration office where the respondent's views were presented. If materials are submitted within 10 calendar days after receipt of the copy of the summary or transcription of the presentation, as applicable, they will be considered before a final decision as to whether or not to recommend prosecution. Any materials received after the supplemental response period generally will be considered only if the final agency decision has not yet been made.

(h)(1) When consideration of a criminal prosecution recommendation involving the same violations is closed by the Commissioner with respect to all persons named in the notice, the Commissioner will so notify each person in writing.

(2) When it is determined that a person named in a notice will not be included in the Commissioner's recommendation for criminal prosecution, the Commissioner will so notify that person, if and when the Commissioner concludes that notification will not prejudice the prosecution of any other person.

(3) When a United States attorney informs the agency that no persons recommended will be prosecuted, the Commissioner will so notify each person in writing, unless the United States attorney has already done so.

(4) When a United States attorney informs the agency of intent to prosecute some, but not all, persons who had been provided an opportunity to present views and were subsequently named in the Commissioner's recommendation for criminal prosecution, the Commissioner, after being advised by the United States attorney that the notification will not prejudice the prosecution of any other person, will so notify those persons eliminated from further consideration, unless the United States attorney has already done so.

[44 FR 12168, Mar. 6, 1979]

§ 7.87 Records related to opportunities for presentation of views conducted before report of criminal violation.

(a) Records related to a section 305 opportunity for presentation of views constitute investigatory records for law enforcement purposes and may include inter- and intra-agency memorandums.

(1) Notwithstanding the rule established in § 20.21 of this chapter, no record related to a section 305 presentation is available for public disclosure until consideration of criminal prosecution has been closed in accordance with paragraph (b) of this section, except as provided in § 20.82 of this chapter. Only very rarely and only under circumstances that demonstrate a compelling public interest will the Commissioner exercise, in accordance with § 20.82 of this chapter, the authorized discretion to disclose records related to a section 305 presentation before the consideration of criminal prosecution is closed.

(2) After consideration of criminal prosecution is closed, the records are available for public disclosure in response to a request under the Freedom of Information Act, except to the extent that the exemptions from disclosure in subpart D of part 20 of this chapter are applicable. No statements obtained through promises of confidentiality shall be available for public disclosure.

(b) Consideration of criminal prosecution based on a particular section 305 notice of opportunity for presentation of views shall be deemed to be closed within the meaning of this section and § 7.85 when a final decision has been made not to recommend criminal prosecution to a United States attorney based on charges set forth in the notice and considered at the presentation, or when such a recommendation has been finally refused by the United States attorney, or when criminal prosecution has been instituted and the matter and all related appeals have been concluded, or when the statute of limitations has run.

(c) Before disclosure of any record specifically reflecting consideration of a possible recommendation for criminal prosecution of any individual, all names and other information that

would identify an individual whose prosecution was considered but not recommended, or who was not prosecuted, shall be deleted, unless the Commissioner concludes that there is a compelling public interest in the disclosure of the names.

(d) Names and other information that would identify a Food and Drug Administration employee shall be deleted from records related to a section 305 presentation of views before public disclosure only under § 20.32 of this chapter.

[44 FR 12168, Mar. 6, 1979]

PART 10—ADMINISTRATIVE PRACTICES AND PROCEDURES

Subpart A—General Provisions

Subpart B—General Administrative Procedures

Subpart C—Electronic Media Coverage of Public Administrative Proceedings; Guideline on Policy and Procedures

AUTHORITY: 5 U.S.C. 551–558, 701–706; 15 U.S.C. 1451–1461; 21 U.S.C. 141–149, 321–397, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201, 262, 263b, 264.

SOURCE: 44 FR 22323, Apr. 13, 1979, unless otherwise noted.

EDITORIAL NOTE: Nomenclature changes to part 10 appear at 68 FR 24879, May 9, 2003.

Subpart A—General Provisions

§ 10.1 Scope.

(a) Part 10 governs practices and procedures for petitions, hearings, and other administrative proceedings and activities conducted by the Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and other laws which the Commissioner of Food and Drugs administers.

(b) If a requirement in another part of title 21 differs from a requirement in this part, the requirements of this part apply to the extent that they do not conflict with the other requirements.

(c) References in this part and parts 12, 13, 14, 15, and 16 to regulatory sections of the Code of Federal Regulations are to chapter I of title 21 unless otherwise noted.

(d) References in this part and parts 12, 13, 14, 15, and 16 to *publication*, or to the day or date of publication, or use of the phrase *to publish*, refer to publication in the FEDERAL REGISTER unless otherwise noted.

[44 FR 22323, Apr. 13, 1979, as amended at 54 FR 9034, Mar. 3, 1989; 69 FR 17290, Apr. 2, 2004]